

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

Case No. 2:18-cr-20800

HONORABLE STEPHEN J. MURPHY, III

v.

D-1 RAJENDRA BOTHRA,  
D-3 GANIU EDU,  
D-4 DAVID LEWIS,  
D-5 CHRISTOPHER RUSSO,

Defendants.

**OPINION AND ORDER  
DENYING MOTION TO DISMISS  
COUNTS 43 AND 53 OF THE INDICTMENT [312]**

Defendants are four physicians who were licensed to practice medicine in Michigan. ECF 1, PgID 6–8. Each Defendant was named in a 56-count indictment the Court ordered unsealed in late 2018. *See generally* ECF 1; 9. Defendants were charged with health care fraud conspiracy under 18 U.S.C. § 1349; aiding and abetting health care fraud under 18 U.S.C. §§ 2 and 1347; conspiracy to distribute and possess with intent to distribute controlled substances under 21 U.S.C. §§ 841(a)(1) and 846; and aiding and abetting the unlawful distribution of controlled substances under 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2. *See generally* ECF 1. All four Defendants are scheduled for trial on May 17, 2022.<sup>1</sup> ECF 329, PgID 2405.

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<sup>1</sup> Two other Defendants pleaded guilty and will not face trial. ECF 301; 364

One Defendant, Dr. David Lewis, moved to dismiss counts 43 and 53 of the indictment. ECF 312. The other Defendants filed notices of joinder and concurrence in Dr. Lewis's motion. ECF 314; 315; 321. The Court will deny the motion.<sup>2</sup>

### BACKGROUND

Defendant Dr. Rajendra Bothra owned and operated two professional limited liability companies—The Pain Center and The Interventional Pain Center—located in Southeast Michigan. ECF 1, PgID 6. The two facilities were participating providers with Medicare and Medicaid and would submit claims for reimbursement to the federal programs. *Id.* Dr. Bothra and the other Defendants—Dr. Ganiu Edu, Dr. Lewis, and Dr. Christopher Russo—were licensed physicians in Michigan and enrolled as participating providers with Medicare at the two companies. *Id.* at 6–8. All six indicted Defendants were also licensed by the Drug Enforcement Administration to prescribe controlled substances. *Id.*

Well over half the counts in the indictment involve health care fraud charges. *See generally* ECF 1. Dr. Lewis does not challenge any of the health care fraud counts in the present motion. *See generally* ECF 312. Instead, the motion focused on count 43, conspiracy to distribute and possess with intent to distribute controlled substances, and count 53, aiding and abetting the unlawful distribution of controlled substances. *Id.*; *see also* ECF 1, PgID 27–28, 31 (indictment). Count 43 specified that “prescription opioids were distributed outside the usual course of professional

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<sup>2</sup> Based on the parties' briefing, the Court will resolve the motion on the briefs without a hearing. *See* E.D. Mich. L. Crim. R. 12.1; E.D. Mich. L.R. 7.1(f)(2).

medical practice, all in violation of Title 21, United States Code, Sections 846, 841(a)(1).” ECF 1, PgID 27–28. Similarly, count 53 stated that “controlled substances were distributed outside the usual course of professional medical practice” before listing the date, patient, controlled substance, and dosage that constituted the offense. *Id.* at 31.

While the grand jury charged all four Defendants in count 43, count 53 only pertains to Dr. Lewis. *See generally* ECF 1. The grand jury charged each Defendant in separate counts for aiding and abetting the unlawful distribution of controlled substances. *See generally id.* The counts pertaining to Dr. Bothra are 44, 45, and 46, the counts pertaining to Dr. Edu are 51 and 52, and the count pertaining to Dr. Russo is 54. *Id.* at 28–32. The language used in count 53 and the language used in the counts pertaining to the other Defendants are identical. *Id.* In their notices of joinder and concurrence, Dr. Bothra, Dr. Edu, and Dr. Russo requested that the Court consider the aiding and abetting the unlawful distribution of controlled substances counts against them in addition to count 53. ECF 314; 315; 321.

At bottom, the motion to dismiss revolves around whether the language in the indictment is sufficient to charge a medical professional with a controlled substances offense. When medical professionals are charged with a controlled substances offense based on prescriptions they issued, the Food and Drug Administration’s regulations govern whether the prescriptions were lawful or unlawful. The precise regulation at issue is 21 C.F.R. § 1306.04(a):

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Defendants argued that an indictment of a medical professional must allege (1) a prescription was not for a legitimate medical purpose *and* (2) not in the usual course of professional practice. *See generally* ECF 312. In other words, Defendants read the first sentence of the regulation in the conjunctive. *Id.* at 2281–82. Because the sentence states what is lawful, the converse states what is unlawful, which, under Defendants’ reading, requires a prescription to be (1) not for a legitimate medical purpose *and* (2) not in the usual course of professional practice to violate the law. *Id.* at 2281. And because the indictment refers only to the prescriptions not being in the usual course of professional practice—and omits reference to whether the prescriptions had a legitimate medical purpose—Defendants claim that the indictment is insufficient and must be dismissed. *See generally* ECF 312.

The Government read the regulation’s first sentence in the disjunctive and urged the Court to deny Defendants’ motion. *See generally* ECF 331. According to the Government, a medical professional can be found guilty if a prescription was either not for a legitimate medical purpose *or* not in the usual course of professional practice. *See generally id.* The Government also argued that the motion was

untimely<sup>3</sup> and that the indictment is sufficient regardless of whether the first sentence of the regulation is read in the conjunctive or disjunctive. *Id.* at 2417–19.

### LEGAL STANDARD

Under Federal Rule of Criminal Procedure 7(c)(1), an indictment “must be a plain, concise, and definite written statement of the essential facts constituting the offense charged and must be signed by an attorney for the government.” In general, “an indictment is sufficient if it, first, contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and, second, enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense.” *Hamling v. United States*, 418 U.S. 87, 117 (1974) (citations omitted). An indictment contains the elements of the offense charged if the indictment “fully, directly, and expressly” states each element of the offense. *United States v. Howard*, 947 F.3d 936, 943 (6th Cir. 2020) (quotation omitted).

### DISCUSSION

The plain text of the regulation requires that the Court read the first sentence of 21 C.F.R. § 1306.04(a) in the conjunctive. The sentence describes what makes a prescription effective. A lawful prescription needs to “be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). Nothing in the regulatory text suggests that a prescription can be effective if written *only* for a legitimate medical purpose

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<sup>3</sup> Because the Court will deny the motion on the merits, the Court need not resolve issues about the motion’s timeliness.

*but not* in the usual course of professional practice. Similarly, nothing in the regulatory text suggests that a prescription can be effective if written *only* in the usual course of professional practice *but not* for a legitimate medical purpose. For a prescription to be effective, therefore, the prescription must be both (1) for a legitimate medical purpose *and* (2) in the usual course of professional practice. *See* 21 C.F.R. § 1306.04(a). In other words, the Court must read the regulation's first sentence in the conjunctive. *See id.* And since the regulation states that a lawful prescription must be both for a legitimate medical purpose *and* in the usual course of professional practice, the logical converse is that if a prescription is either not for a legitimate medical purpose *or* not in the usual course of professional practice, the prescription is unlawful. While the regulation is written in the conjunctive, the contrapositive, a statement of conduct that violates the law, must be formed in the disjunctive. Thus, throughout this Order, the Court will refer to the first sentence's converse because that is the standard at issue in the indictment and it is the manner in which courts throughout the federal judiciary refer to the sentence.

The regulation's last sentence also suggests that a prescription only need not be provided in the usual course of professional practice to violate the law. The sentence provides that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription" under federal law and "the person issuing it[] shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. § 1306.04(a). On its face, the last sentence's structure would

have any prescription not in the usual course of professional treatment violate the law if the prescription is for a controlled substance.

Despite the plain meaning of the regulatory text, decades of convoluted Sixth Circuit case law has muddled the waters on whether: (a) a prescription must be both not for a legitimate medical purpose *and* not in the usual course of professional practice, (b) one or the other, or (c) only not in the usual course of professional practice to violate the law. While the Sixth Circuit has looked to 21 C.F.R. § 1306.04(a) to review controlled substances convictions of doctors, the Circuit has never directly addressed whether the regulation’s first sentence is written in the conjunctive or disjunctive. *United States v. Oppong*, No. 21-3003, 2022 WL 1055915, at \*5 n.4 (6th Cir. Apr. 8, 2002).

One of the first times the Sixth Circuit discussed the regulation was in *United States v. Kirk*, 584 F.2d 773 (6th Cir. 1978). There, the Sixth Circuit stated that “two of the essential elements of” a controlled substances violation by a medical professional are that “[t]he prescriptions issued by the [defendant] to various persons must have been ‘not in the usual course of professional practice’ *and* ‘not for a legitimate medical or research purpose.’” *Id.* at 784 (emphasis added). The excerpt from *Kirk* is seemingly a fatal blow to the Government’s argument. But the rest of *Kirk*, rather remarkably, resuscitates the Government’s case.

The turnaround starts in the opinion’s next sentence when the Sixth Circuit noted that “[i]t has been held that there is no difference in the meanings of the statutory phrase, ‘[i]n the usual course of professional practice’ and the regulations’

phrase, ‘legitimate medical purpose.’” *Id.* (citations omitted). In other words, the two elements were actually a single element. *See id.* The Sixth Circuit’s note that the two phrases lack a distinction explains why the court used the disjunctive ‘or’ to recite the element the Government had to prove to obtain a proper conviction.<sup>4</sup> If anything, *Kirk* supports reading the regulation to require an unlawful prescription either not be for a legitimate medical purpose *or* not be in the usual course of professional practice—not both. *Kirk*, however, “did not directly address the disjunctive/conjunctive issue.” *Oppong*, 2022 WL 1055915, at \*5, n.4.

Two years later, the Sixth Circuit changed course and held that “a conviction under § 841(a)(1) requires the government to prove beyond a reasonable doubt that

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<sup>4</sup> For example, *Kirk*, 584 F.2d at 782 (“Each of counts two through forty eight charged appellant with having caused the distribution of a controlled substance by issuing a written order, purporting to be a prescription, for a named individual, not in the usual course of professional practice *or* for legitimate medical or research purpose.”), 783 (“The prosecution, however, did present Larry Craig who was named in counts nine, ten, eleven and twelve as having been wrongfully issued prescriptions . . . which prescriptions were not issued in the usual course of appellant’s professional practice *or* for a legitimate medical or research purpose.”), 783–84 (“These four prescriptions formed the basis for the prosecution in counts nine, ten, eleven and twelve as having been wrongfully issued to Craig by appellant not in the usual course of professional practice *or* for a legitimate medical or research purpose, in violation of 21 U.S.C. § 841(a)(1).”), 785–86 (“This testimony was sufficient from which the jury could have drawn inferences that the issuance of prescriptions for controlled drugs was not in the usual course of professional practice *or* for a legitimate medical or research purpose.”), 786 (“We have previously indicated that there is sufficient evidence from which the jury could infer that the appellant issued prescriptions, to individuals for controlled substances, not in the course of professional practice *or* for a legitimate medical or research purpose” and “these are elements of substantive counts” related to controlled substances violations.), 787 (“We conclude that there is ample evidence from which the jury could find that the appellant issued prescriptions . . . that [] were not issued in the usual course of professional practice *or* for a legitimate medical or research purpose.”) (all emphases added).



the drugs were distributed outside the usual course of professional practice.” *United States v. Seelig*, 622 F.2d 207, 213 (6th Cir. 1980) (citations omitted). What is more, *Seelig* severely undermines Defendants’ motion because the Sixth Circuit held that whether indictments do not explicitly charge medical professionals with language from the regulation related to their capacities as medical professionals is “immaterial” since an indictment of a medical professional under § 841(a)(1) “necessarily implies that a registered doctor or other practitioner is acting outside the usual course of professional conduct.” *Id.* at 216. No matter how the regulation is read, the indictment is therefore sufficient.

Only more than a decade later did the Sixth Circuit suggest that a prescription must be (1) not for a legitimate medical purpose *and* (2) not in the usual course of professional practice for a doctor to be found guilty of a controlled substances violation. In *United States v. August*, the Sixth Circuit stated that “because [Defendant] is a doctor, the government needed to prove . . . that the distribution occurred outside the usual course of professional practice *and* for no legitimate medical purpose.” 984 F.2d 705, 712 (6th Cir. 1992) (emphasis added) (collecting cases). But in formulating the standard in *August*, the Sixth Circuit cited and relied primarily on *Kirk* and *Seelig*, neither of which, as discussed above, suggest that a

prescription must be (1) not for a legitimate medical purpose *and* (2) not in the usual course of professional practice.<sup>5</sup> *Id.*

Because the *August* panel could not overturn *Kirk* and *Seelig*, *August* simply misstated the Sixth Circuit’s longstanding precedent. *See United States v. Lanier*, 201 F.3d 842, 846 (6th Cir. 2000) (citation omitted) (reaffirming that a three-judge panel cannot overturn the decision of another panel because only an en banc panel can overturn that sort of decision). And the misstatement created the convoluted case law that makes interpreting 21 C.F.R. § 1306.04(a) tougher than the interpretation should be given the regulation’s plain text.

Later Sixth Circuit cases, such as *United States v. Volkman*, 797 F.3d 377 (6th Cir. 2015) and *United States v. Godofsky*, 943 F.3d 1011 (6th Cir. 2019), mistakenly used the *August* formulation instead of the original *Kirk* and *Seelig* formulations that were never overruled.<sup>6</sup> And while the *Volkman* jury instructions are the model instructions for controlled substances cases against doctors, the correct instructions for “legitimate medical purpose” and “usual course of professional practice” must have

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<sup>5</sup> The *August* panel also relied on *United States v. Varma*, 691 F.2d 460, 462 (10th Cir. 1982). Since *Varma*, the Tenth Circuit has held that “[n]othing in the analysis or rationale of [*Varma*] is dependent on the recitation of the element in question in the conjunctive.” *United States v. Nelson*, 383 F.3d 1227, 1232 (2004). To that end, the Tenth Circuit has adopted the disjunctive reading that the Government has argued for in their response to the present motion. *Id.* at 1232–32 (affirming a jury instruction that used a disjunctive reading of the regulation).

<sup>6</sup> In both cases, the Sixth Circuit did not directly address the conjunctive/disjunctive issue because the issue was never raised.

“or” between them instead of “and” to comply with Sixth Circuit precedent dating back to the 1970s.

To be sure, the Sixth Circuit recently upheld jury instructions under plain-error review that were in the disjunctive. *Oppong*, 2022 WL 1055915, at \*4–5. In the Sixth Circuit’s words, “binding case law does not support [the conjunctive reading of the] jury-instructions.” *Id.* at \*5.

The Court will therefore deny Defendants’ motion to dismiss the counts of the indictment related to controlled substances violations for two reasons. First, under *Seelig* the Government did not need to add language specific to medical professionals in the indictment because reference to the statutory provision implied that the doctors acted outside the course of professional practice. And second, the Government’s reading of the regulation complies with Sixth Circuit precedent; only one of the phrases, not for a legitimate medical purpose *or* not in the usual course of professional practice, needed to be alleged in the indictment.

### CONCLUSION

The issues presented to the Court in the briefs will likely appear again when the jury instructions for the trial are submitted to the Court. The parties should use this Order to form the jury charge and argue for and against certain language in the instructions based on the above. The parties should also “note that the Supreme Court has granted certiorari in *Kahn v. United States*, No. 21-5261, in which one of the questions presented is: ‘Should the usual course of professional practice and legitimate medical purposes prongs of [21] C.F.R. § 1306.04(a) be read in the

conjunctive or the disjunctive?” *Oppong*, 2022 WL 1055915, at \*5 n.5 (citation omitted). But that fact should not come as a surprise to the parties because the Court notified them of the grant of certiorari last year. ECF 310, PgID 2257–58 (“After closely reviewing the filings on the Supreme Court’s docket in [*Kahn*], the Court finds that the question presented in [*Kahn*] directly impacts . . . decisions about crucial jury instructions the Court would provide at trial.”).

**ORDER**

**WHEREFORE**, it is hereby **ORDERED** that the motion to dismiss counts 43 and 53 of the indictment [312] is **DENIED**.

**SO ORDERED.**

s/ Stephen J. Murphy, III  
STEPHEN J. MURPHY, III  
United States District Judge

Dated: May 11, 2022

I hereby certify that a copy of the foregoing document was served upon the parties and/or counsel of record on May 11, 2022, by electronic and/or ordinary mail.

s/ David P. Parker  
Case Manager